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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,264	11/30/2001	Gordon Lowe	2001-1187A	2270

513 7590 11/29/2004

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EXAMINER	
COVINGTON, RAYMOND K	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,264	LOWE, GORDON	
	Examiner	Art Unit	
	Raymond Covington	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *9-18* is/are allowed.

6)☒ Claim(s) *1-7,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC. 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over McFadyen et al Biochem. J. (1986) v. 238, pp 757-763 in view of McCoubrey et al FEBS Letters 380 (1996) pp 73-78, McFadyen et al Biochem. J. (1987) v. 242, pp. 177-183, Peyratout et al Inorg. Chem. 1995, v. 34, pp 4484-4489 and Mureinik et al Inorg. Nucl. Chem. Letters v. 13 pp 625-629 (1977).

The references are applied as in the previous office action. Claims 9-10 have been withdrawn in light of applicants' amendment as they are no longer obvious over the cited art. McFadyen et al Biochem. J. (1986) v. 238, pp 757-763 teach platinum (II) terpyridine complexes of the same type recited in the claims. See page 757. McCoubrey et al FEBS Letters 380 (1996) pp 73-78 teach analogous complexes. See page 73 right column section 2 formula I. As does McFadyen et al Biochem. J. (1987) v. 242, pp. 177-183, see page 177 figure 1, and Mureinik et al Inorg. Nucl. Chem. Letters v. 13 pp 625-629 (1977), last paragraph.

The references differ in that exemplification for the entire scope of compounds inclusive in the recited claims is not given. It is noted however, that it is not required that every compound under the generic claims be exemplified. The generic description together with the examples from the cited references would place the claimed compounds in possession by the skilled artisan in the field.

The claimed invention would have been obvious to one of ordinary skill in the art in view of the prior art as a whole as the use of somewhat different but otherwise analogous substituents in lieu of those taught in the cited references would not have been unexpected. This is particularly true in further view of Peyratout et al Inorg. Chem. 1995, v. 34, pp 4484-4489 which teach bifunctional complexes of the type claimed to be known in the art.

Claims 19-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the treatment of all human thioredoxin reductase inhibited diseases or conditions as well as anti-protozoal, anti-rheumatoid arthritis or anti-tumor agent. Further, The claims 19-20 read on affecting various biochemical pathways, thereby failing to set forth a definable utility. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described.

1) quantity of experimentation necessary,
2) the amount of guidance presented,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the predictability of the art,
7) breath of the claims and
8) The level of skill in the art.

The nature of the invention in claims 19-20 is the treatment the treatment of all human thioredoxin reductase inhibited diseases or conditions as well as anti-protozoal, anti-rheumatoid arthritis or anti-tumor agent.

The instant claimed invention is highly unpredictable as discussed below:

The state of the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that compounds of claim 1 would affect the possible treatment of any human thioredoxin reductase inhibited diseases or

conditions as well as anti-protozoal, anti-rheumatoid arthritis or anti-tumor agent or inhibited.

Hence, in the absence of a showing of correlation between all the diseases claimed as capable of treatment by the compound of claim 1 the inhibition of human thioredoxin reductase, one of skill in the art is unable to fully predict possible results from the administration of the compound of claim 1 due to the unpredictability of the role of human thioredoxin reductase, i.e. whether promotion or inhibition would be beneficial for the treatment of the diseases.

The nature of pharmaceutical arts is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The direction present in the instant specification is that the compounds of claim 1 can inhibit human thioredoxin reductase. However, the specification is silent and fails to provide guidance as to whether the diseases listed as human thioredoxin reductase diseases require the inhibition of human thioredoxin

reductase for treatment, i.e. the specification fails to provide a correlation between the diseases listed and the inhibition of human thioredoxin reductase.

The breadth of the claims is that the compound of claim 1 can treat any human thioredoxin reductase inhibited diseases or conditions as well as anti-protozoal, anti-rheumatoid arthritis or anti-tumor agent diseases.

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what diseases would be benefited by any human thioredoxin reductase inhibition and would furthermore then have to determine whether the claimed compounds would provide treatment of the disease by any human thioredoxin reductase inhibition. Claims directed to mediating a biochemical pathway are devoid identifiable utility and are therefore not useful unless the pathway at issue is critical to treating some condition and the pathway modification and disease treatment are inexorably linked by factual evidence, a claim to the pathway modification is devoid of utility.

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support and exemplification of the broad use of the compound of the claim 1 for the treatment of any human thioredoxin reductase inhibited disease. As a result necessitating one of skill to perform an exhaustive search for which diseases can be treated by the compounds of claim 1 in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001 , states that " a patent is not a hunting license. It is not a reward for search , but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Further, Claims 19-20 are rejected under 35 U.S.C. 1 12, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Please note that claims 21-22 are considered being "reach through" claims which contain subject matter to be discovered in the future i.e. any disorder not yet correlated but may be discovered in the future with human thioredoxin reductase inhibition.

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases or condition can be treated by the compound encompassed in the instant claims, with no assurance of success.

This rejection can be overcome deleting claims 19-20.

Claims 9-18 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond Covington
Examiner
Art Unit 1625

RKC